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EXAMINER	
HOWARD, ZACHARY C	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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SEATTLE, WA 98119

In re Application of:
Brockhaus et al.
Serial No.: 08/444,790
Filed: May 19, 1995
Attorney Docket No.: 9189

: PETITION DECISION

This is in response to the Petition filed by Applicants under 37 CFR § 1.181 on November 21, 2008, requesting reconsideration of the decision rendered September 23, 2008 which denied Applicant's allegation that the examiner presented a new ground of rejection instituted in the Examiner's Answer mailed August 14, 2008 upon communicating to applicants that the full-length extracellular domain of a 75 kD human TNF receptor was not representative of the genus of receptors provided by the claimed invention. Applicants request reconsideration by the Director in favor of Applicants and further request correction of the Examiner's Answer by identifying the alleged new ground of rejection made by the examiner of record therein.

BACKGROUND

On April 3, 2006, the examiner mailed a non-final Office action setting a three month statutory limit for reply. At the time this Office action was mailed, claims 62, 66, 67, 102-107, 110-114 and 119-138 were pending and examined. *Inter alia*, the examiner rejected claims 123, 124, 132 and 133 under 35 U.S.C. § 112, first paragraph, as lacking enablement, rejected claims 62, 66, 67, 102-107, 110-114 and 119-138 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement and rejected claims 62, 66, 67, 102-107, 110-114, 119-122, 125-131 and 134-138 under 35 U.S.C. 103(a) as being unpatentable over Dembic et al (Cytokine, Vol. 2, No. 4 (July) 1990: 231-237) in view of Capon et al, U.S. Patent No. 5,116,964.

On June 26, 2006, the examiner held an in-person interview with applicants' representatives as well as Inventor Werner Lesslauer. Gary Nickol (Supervisor) and Elizabeth Kemmerer (Primary Examiner) were also in attendance.

In formal reply to the non-final Office action mailed April 3, 2006, applicants filed a response including arguments in traversal of the examiner's rejections, amendments to the claims and a Declaration of Biological Deposit on October 6, 2006. As applicants point out in the petition,

the relevant portion of applicants' response pertaining to the issues of their petition included a discussion of their alleged unexpected results which were discussed in the Interview held on June 26, 2006. Specifically, Applicants discussion included:

> During the interview, Applicants discussed the trimeric nature of tumor necrosis factor (TNF) alpha and the homodimeric nature of the claimed fusion proteins, which comprise soluble fragments of p75 tumor necrosis factor receptor (TNFR) fused to all of the domains of the constant region of a human immunoglobulin IgG heavy chain other than the first domain (CH1) of said constant region. The immunoglobulin portion of the claimed fusion protein, which includes the hinge, second domain (CH2), and third domain (CH3) of the heavy chain constant region, naturally homodimerizes through cysteine bonding between the two hinge regions. (Response of October 3, 2006, page 10)

Applicants additionally filed a subsequent reply on November 14, 2006 which also included arguments, claim amendments, and a Declaration filed by Dr. Werner Lesslauer.

The examiner mailed a final Office action on February 23, 2007 setting a three month statutory limit for reply. At the time this non-final Office action was mailed, claims 62 102 103 105-107 110, 111, 113, 114, 119-121, 123-137 and 139-144 were pending, claim 139 being withdrawn from examination on the merits as being directed toward a non-elected invention. The examiner maintained the rejection of claims 62, 102, 103, 105, 106, 107, 110, 111,113, 114, 119-121 and 123-137 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement and further maintained the rejection of claims 62, 102, 103, 105, 106, 107, 110, 111,113, 114, 119-121,125-131 and 134-137 under 35 U.S.C. 103(a) as being unpatentable over Dembic et al. in view of Capon et al.. The examiner additionally instituted a new rejection over claims 140-144 under 35 U.S.C. § 112, first paragraph, for lacking enablement and failing to comply with the written description requirement. Notably, in this final Office action, the examiner considered applicants' assertions of unexpected results:

> Applicants further argue that the 103 rejection should be withdrawn in view of a number of unexpected results associated with the claimed TNF-binding fusion proteins. Applicants present data supporting three categories of unexpected results: lack of aggregation ability; markedly reduced immunoglobulin effector function; and "binding affinity, kinetic stability and potency". Applicants' arguments have been fully considered but are not found persuasive. The evidence of unexpected results presented by Applicants is not sufficient to overcome the rejection. Applicants' putative unexpected results appear to be generated using a fusion protein comprising the full-length extracellular domain of the insoluble 75 kD TNF binding receptor and portions of an immunoglobulin molecule. However, as set forth above, in the section "Claim Rejections - 35 U.S.C. 112, 1st paragraph, written description", the specification does not provide a description of this particular species of fusion protein. There is no conception in the specification at the time of filing of this particular species of fusion protein. Therefore, the evidence of unexpected results found with this particular species of receptor-Ig fusion is not sufficient to overcome the obviousness of combining the teachings of Dembic in view of Capon. (final Office action, pp. 18-19)

On August 6, 2007, Applicants filed an amendment after final Office action under 37 CFR § 1.116 which included arguments, three Declarations and claim amendments. Two of said Declarations were filed under 37 CFR § 1.132 by Stewart Lyman; said Declarations were filed in an attempt to corroborate applicants' assertion that claims 62, 102, 103, 105, 106, 107, 110, 111,113, 114, 119-121 and 123-137 fulfilled the written description requirement.

On October 9, 2007, the examiner mailed an Advisory Action indicating that the amendment filed by Applicants on August 6, 2007 would not be entered due to the introduction of new matter into the claims. The examiner did however, answer relevant arguments posed by applicants in the amendment filed August 6, 2007 and also considered the three Declarations submitted concurrently with said amendment.

On February 2, 20 08, applicants filed an Appeal Brief under 37 CFR § 1.17(b).

On August 14, 2008 an Examiner's Answer was mailed by the examiner.

On August 28, 2008 applicants filed a Petition under 37 CFR § 1.181 requesting that the Director acknowledge the alleged new grounds of rejection instituted in the Examiner's Answer mailed August 14, 2008. Applicants requested correction of the Examiner's Answer by mailing a new Examiner's Answer which identifies the alleged new ground of rejection made by the examiner of record therein. Applicants' first allegation pertaining to a new ground of rejection focused on the contention that the examiner instituted a new ground of rejection upon substantively considering applicants' evidence regarding unexpected results for the first time in the Examiner's Answer. The second allegation raised by applicants in the petition concerned the examiner's articulation, for the first time in the Examiner's Answer, that monomeric fusion proteins missing a hinge domain made obvious the claimed invention.

On September 23, 2008 a Petition Decision was mailed by Granting the petition filed on August 28, 2008. Said Petition indicated to applicants that the examiner's substantive discussion in the Examiner's Answer of applicants' data filed by applicants to support an unexpected result was not considered a new ground of rejection and thus, applicants' arguments on this matter were not accepted. Said Petition however, additionally indicated that applicants' allegation that the examiner articulated, for the first time in the Examiner's Answer, that monomeric fusion proteins missing a hinge domain made obvious the claimed invention was found persuasive and hence the Petition was Granted in favor of applicants.

On November 21, 2008 applicants filed a renewed petition under 37 CFR § 1.181 requesting further review at a higher level of the Decision of September 23, 2008.

DISCUSSION

The petition and the file history have been carefully considered.

The examiner has mailed a new Examiner's Answer omitting the new rejection instituted in the Examiner's Answer pertaining to the new motivation for combining the Dembic and Capon references as requested in applicants' first petition filed on August 28, 2008. Secondly, the examiner has omitted any instance pertaining to wherein the full-length extracellular domain of a 75 kD human TNF receptor shown to have unexpected results, yet lacking written description, is not representative of the genus of receptors as claimed as requested in this Petition, thus rendering this Petition moot.

DECISION

The petition is **DISMISSED AS MOOT.**

Should there be any questions about this decision please contact Marianne C. Seidel, by letter addressed to Director, TC 1600, at the address listed above, or by telephone at 571-272-0584 or by facsimile sent to the general Office facsimile number, 703-872-9306.

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